RESPONSE UNDER 37 C.F.R. § 1.116

Application No.: 10/812,075

REMARKS

I. Status of Claims

Claims 2, 52-67, 69-96, 99-101, 103-106 and 112 are pending in the application.

Claims 52-56, 59-62, 65-67, 69-71, 73, 74 and 104-106 are withdrawn from

consideration.

Claims 2, 75-77, 79, 82-85, 88-90, 93, 94, 100, 103 and 112 are rejected.

Claims 57, 58, 63, 64, 72, 78, 80, 81, 86, 87, 91, 92, 95, 96, 99 and 101 are objected to.

II. Restriction and Species Election

Applicants thank the Examiner for acknowledging Applicants' request for rejoinder of method claims, and holding rejoinder in abeyance pending determination of the allowability of the compound and composition claims.

III. Response to Rejection under 35 U.S.C. § 103

The Office has maintained the rejection of claims 2, 75-77, 79, 82-85, 88-90, 93, 94, 100, 103 and 112 under 35 U.S.C. §103(a) as allegedly being obvious over Wustrow et al. (*J. Med. Chem.* 1998, 41(5):760-771; "Wustrow"). Wustrow was cited in the previous Actions and is not discussed in full detail herein for purpose of brevity.

In the Action, the Office asserts that the following compounds of Wustrow renders the claimed subject matter of the above claims obvious.

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1. RN 204245-70-5, 2-Pyrimidinamine, N-[4-[2-[methyl(phenylmethyl)amino]ethyl]cyclohexyl]-, trans-,

2. RN 204245-89-6, 2-Pyrimidinamine, N-[4-[2-(dipropylamino)ethyl]cyclohexyl]-,

and,

3. RN 189153-07-9, Cyclohexaneacetic acid, 4-(2-pyrimidinylamino)-, ethyl ester,

Also, Applicants note that the Office asserts a Rule 1.132 Declaration by Mr. Kanuma ("Kanuma Declaration (1)"), which was submitted with Amendment under 1.116 filed April 8, 2008, is not fully persuasive because Compound 1 of the Kanuma Declaration (1) is not the compound of the Wustrow reference, because the Wustrow compound has a methylene between the phenyl ring and the amino whereas Compound 1 of the Kanuma Declaration (1) has an ethylene between the phenyl ring and the amino. The Office also further asserts that the test should be repeated with the correct closest prior art compound compared directly to the closest compound of the claimed invention.

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Applicants respectfully traverse the rejection as following and submit a second Rule 1.132 Declaration with the Response. Applicants respectfully request that the Office consider the second Rule 1.132 Declaration and reconsider the application.

1. Compound 1 of the Kanuma Declaration (1) is Equivalent to Compound 36 of
Wustrow:

As stated at paragraphs 3, 5 and 6 of the accompanying second Rule 1.132 Declaration, Wustrow does not disclose the compound "RN 204245-70-5, 2-Pyramidinamine, N-[4-[2-methyl(phenylmethyl)amino]ethyl]cyclohexyl]-, trans", as asserted by the Examiner. Instead, Wustrow discloses N-[trans-4-[2-methyl(phenylethyl)amino]ethyl]cyclohexyl]pyrimidin-2-amine (compound 36 at Table 1, page 764), which is similar to compound 18 of the presently claimed invention. Therefore, it is believed that the Kanuma Declaration (1) compares the closest prior art compound to the closest claimed compound. Nevertheless, in order to advance the prosecution, Applicants conducted additional tests and file herewith the results of the tests in a form of Rule 1.132 Declaration.

2. The Kanuma Declaration (2)

The presently claimed compounds contain a 1,4-<u>cis</u>-cyclohexyl moiety within the structure, as represented by the group "L" in claim 2. – In contrast, the compounds of Wustrow contain a 1,4-<u>trans</u>-cyclohexyl structure, as depicted above. Therefore, the Wustrow compounds are clearly distinguishable over the presently claimed compounds.

The second Rule 1.132 Declaration executed by Mr. Kanuma, a copy of which is submitted herewith ("Kanuma Declaration (2)") compares the properties of a presently claimed compound, which is considered to be the closest compound to Wustrow compound, and a reference compound, wherein the two compounds differ only in the configuration of the 1,4-cis-

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cyclohecyl moiety. That is, the claimed compound has a 1,4-<u>cis</u>-cyclohexyl moiety and the reference compound has a 1,4-<u>trans</u>-cyclohexyl moiety.

The synthesis of the compounds tested and the test methods are described in the accompanying Kanuma Declaration (2), and are not repeated herein for brevity.

As can be clearly seen from the Kanuma Declaration (2), the presently claimed compound has remarkable antagonistic activity for the human MCH1 receptor, whereas the reference compound does not show any significant antagonistic activity for the same receptor. Therefore, the presence of the 1,4-cis-cyclohecyl moiety distinguishes the presently claimed invention from the tested reference compound. See paragraphs 6 and 7 of the revised Kanuma Declaration. Such remarkable antagonistic activity was not predicted from teachings of Wustrow by one skilled in the art.

In view of the above, the claimed compounds would not have been obvious to one of ordinary skill in the art.

Therefore, Applicants respectfully request reconsideration and withdrawal of the §103 rejection based on Wustrow.

IV. Response to Claim Objections

Claims 57, 58, 63, 64, 72, 78, 80, 81, 86, 87, 91, 92, 95, 96, 99 and 101 are objected to as being depended from a rejected base claim. However, the Examiner indicates that the above claims would be allowable if re-written in independent form.

Applicants respectfully request that should the above discussed §103 rejection be overcome, the Examiner reconsider and withdraw the objection to claims 57, 58, 63, 64, 72, 78, 80, 81, 86, 87, 91, 92, 95, 96, 99 and 101.

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Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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WASHINGTON OFFICE

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Date: September 5, 2008

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